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**REMARKS****I. Amendments**

Claims 1 and 27 have been amended to delete the term "sequentially" from these claims. Applicants submit that this term is not needed to patentably distinguish the claimed invention over the cited prior art.

In order to expedite prosecution and reduce the number of outstanding issues, method claims 18 and 28 have been amended to depend upon apparatus claims 1 and 27, respectively.

No new matter has been added by any amendment herein.

**II. Rejections under 35 U.S.C. § 103(a) - Apparatus claims**

**A. Claims 1-3, 6-11, 17, and 26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over EP 896,215 to Hammond et al. ("Hammond") in view of EP 767,369 to Trygstad ("Trygstad") and EP 436,338 to Wong ("Wong").**

In the previous Amendment, filed October 5, 2004, the claims were amended to clarify and distinguish the claimed invention over the prior art of record. Specifically, claim 1 was amended to recite that the holding parts are adapted to move between an open and closed position at the analyzing position. In the final Office Action, the Examiner cited Wong as allegedly disclosing holding parts which are adapted to move between an open position when a sample is provided for analysis and a closed position when the sample is analyzed. The Examiner concludes that it would have been obvious, in view of Wong, to modify Hammond and Trygstad to include holding parts which are adapted to open and close at the analyzing position to arrive at the claimed invention.

For the reasons to be presented below, Applicants submit that the combination of Wong destroys the respective intent, purpose and function of Hammond and Trygstad. Accordingly, a *prima facie* case of obviousness has not been established.

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**1. Hammond and Trygstad require the precise location of a tablet in a tablet holder.**

Hammond has already been discussed in Applicants' previous communications. In brief, Hammond discloses that a pharmaceutical tablet is clamped into a sample holder which is then ***manually*** inserted into a spectrometer for analysis (page 6, paragraph [0018]). Thus, in accordance with Hammond, the sample holder is not adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Furthermore, Applicants maintain that Hammond does not disclose or suggest a structural means for feeding the sample through an analyzing position as contemplated by the claimed invention.

Hammond discloses that small vibrations of the tablet, and poor alignment of score lines in the tablet result in "unacceptable variations in the reproducibility of the analysis spectra" (page 4, paragraph [0008]). Hammond addresses this problem by clamping the tablet in the recess of a sample holder by a spring-loaded rod to ensure that the tablet is located and retained at a predetermined position in the recess during analysis. The clamping force ensures that tablets are secured, one after another, relative to the recess with the embossing or score line at a constant position relative to the direction in which the beam is applied to the tablets. The effect of clamping the tablets in the tablet holder permits reproducible analysis measurements to be achieved. (Abstract; and col. 5, lines 32-44).

As with Hammond, Trygstad requires precise alignment of samples to obtain reproducible sample data. Trygstad has also been discussed in Applicants' earlier papers. Trygstad discloses that a solid sample, such as a pharmaceutical tablet, is manually placed in a sample locator and covered with a masking element. The sample locator is then ***manually*** inserted into a slot of a measuring device to obtain a measurement (col. 3, line 56 - col. 4, line 4). Thus, in accordance with Trygstad, the sample holder is not adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Furthermore, Applicants maintain that Trygstad does not disclose or suggest a structural means for feeding the sample through an analyzing position as contemplated by the claimed invention.

Trygstad attempts to obtain reproducible data by minimizing light leakage around the tablet during data collection. In this regard, Trygstad indicates that the dimension of the sample tablet locator are precisely formed in relation to the tablet. Trygstad also discloses that a unique

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sample locator and masking element are provided to obtain a custom fit to the particular dimensions of each tablet form (col. 4, lines 5-11). Therefore, Trygstad uses a sample holder which is essentially custom-designed for each tablet size, and by precisely sizing the diameter of the sample well, the potential for incident light to leak around the sample is minimized (col. 4, lines 15-17), and thereby maximizing the reproducibility of the sample.

In summary, therefore, Hammond and Trygstad are directed to apparatuses and methods for obtaining reproducible data regarding a pharmaceutical tablet by precisely positioning and securing the tablet in a sample holder. Neither Hammond nor Trygstad discloses a sample holder that is adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Rather, to achieve their intended purpose, Hammond and Trygstad disclose a sample holder that is already in a closed position when the sample is provided for analysis and when it is analyzed.

**2. Wong is not suitable for the measurement of pharmaceutical tablets.**

Contrary to Hammond and Trygstad which are directed to the measurement of a pharmaceutical tablet, Wong is directed to the measurement of deformable samples. The only sample type disclosed is rat liver tissues (Abstract; col. 2, lines 37-39; and col. 4, lines 6-9). Applicants submit, therefore, that Wong is not aware of or concerned with the requirements associated with the measurement of non-deformable pharmaceutical tablets to obtain reproducible results.

Specifically, Wong discloses a sample holder for use in non-pressure dependent infrared spectroscopy. The sample holder comprises two windows of infrared light-transmitting material, wherein one of the windows is contoured to provide a sample space between the two windows. A deformable sample is placed in the sample space of the contoured window, and lightly compressed to fill the sample space. The sample holder is then inserted into a spectrometer for analysis (Abstract). As with Hammond and Trygstad, Wong does not disclose or suggest a structural means for feeding the deformable sample through an analyzing position as contemplated by the claimed invention.

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It is Wong's aim to solve the problems with prior art devices that introduced optical interference fringes in the spectra. Wong solves this problem with the sample space having a non-horizontal surface as illustrated in Figures 3-7. While the non-horizontal surface of the sample space may be suitable to hold a deformable sample that fills the entire sample space, none of the sample spaces disclosed by Wong have a surface that conforms to the shape of a pharmaceutical tablet. As such, the sample space disclosed by Wong will not give the precise positioning of tablets in the sample holder and the reproducibility required by Hammond and Trygstad. For this reason alone, there is no motivation to combine Wong with Hammond and Trygstad to arrive at the claimed invention.

**3. Wong defeats the intended purpose and function of Hammond and Trygstad.**

Wong's disclosure of the non-specific placement of a deformable sample in the sample space is incompatible with the requirement by Hammond and Trygstad for the precise placement of a pharmaceutical tablet in a sample holder to obtain reproducible analysis measurements. Furthermore, Wong's disclosure of means 34 for urging the windows 20 and 22 into face-to-face contact to compress and conform the deformable sample to the shape of the sample space (col. 3, lines 48-52) is incompatible with the disclosure by Hammond at column 10, lines 45-48, that probe 40 is spring loaded to alleviate undue pressure being applied to the tablet 20 to ensure that the integrity of the tablet is maintained (page 6, paragraph [0019]).

Moreover, Hammond expressly states that the clamping force is applied in a direction substantially perpendicular relative to the direction in which the beam of electromagnetic radiation is applied to the tablet (page 3, paragraph [0005]). In contrast to Hammond, Wong discloses compression of the deformable sample in a parallel direction relative to the direction of the infrared light beam (Figure 2; col. 3 at line 48 to col. 4, line 5).

In view of the foregoing, Applicants submit that modification of Hammond and Trygstad to include the holding parts of Wong would destroy the structural features and intended purpose of these references. When a §103(a) rejection is based upon a modification of a reference that destroys the function of the invention disclosed in the reference, such a modification is not proper and a *prima facie* case of obviousness cannot be properly made.

Accordingly, the rejection of claims 1-3, 6-11, 17, and 26 under §103(a) is improper and should be withdrawn.

- B. Claim 13 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hammond, Trygstad and US 5,679,954 to Soloman ("Soloman"), and Claims 12, 14-16 and 25 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hammond, Trygstad and DE 4 441 686 to Schilling ("Schilling").**

Each of claims 12-16 and 25 is directly or indirectly dependent on claim 1. However, the Examiner has not cited Wong in combination with Hammond and Trygstad. Instead of Wong, the Examiner has cited Solomon or Schilling. The Examiner has not identified the disclosure by Solomon or Schilling of holding parts adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed.

Accordingly, Applicants rely on the preceding comments in Section II(A), above, and submit that a *prima facie* case of obviousness has not been established. The rejection of claims 12-16 and 25 under §103(a) is improper and should be withdrawn.

### **III. Rejections under 35 U.S.C. § 103(a) – Method claims**

Claims 18-23 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hammond in view of Schilling and Trygstad. Claim 18 has been amended to recite the apparatus of claim 1. Therefore, amended claim 18 requires holding parts to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Applicants submit that the cited prior art, whether taken alone or in combination, does not suggest the "timing" step of amended claim 18 wherein the sample holding parts of the apparatus open and close about the sample at the analyzing position.

Applicants rely on their remarks of record in distinguishing the invention of claims 18-23 over the cited prior art. In this regard, the cited prior art does not suggest a method of analyzing a pharmaceutical sample which comprises temporarily fixing a sample *at an analyzing position* by means of a fixing means which is structurally capable of opening and closing about the sample *at the analyzing position*. Advantageously, the claimed method permits rapid on-line or

at-line analyses of pharmaceutical samples, and reduces or eliminates manual manipulation of the samples, thereby enhancing reproducibility and precision of the data obtained.

In the Office Action at page 11, the Examiner alleges that Hammond discloses two analyzing positions: a first analyzing position where the sample is clamped, and a second analyzing position where the sample is displaced. It appears that the Examiner is equating Hammond's disclosure of a "predetermined position" with Applicants' "analyzing position". Applicants disagree with this characterization of Hammond.

Hammond expressly defines the expression "predetermined position" as "that position in the sample compartment recess to which each tablet of a batch of identical tablets will be displaced by the clamping force irrespective of the initial positioning of the tablet in the recess, and which predetermined position will be the same for all tablets in the batch when the tablets are similarly oriented in the recess" (col. 5, lines 44-51). In other words, the predetermined position refers to a consistent and uniform positioning of tablets in the sample holder which is later inserted into a spectrometer, and not to the placement of the sample in the spectrometer for analysis.

In contrast to Hammond, Applicants' analyzing position is the position where a sample is clamped, irradiated with a measurement beam of radiation, and subsequently released. Accordingly, and contrary to the Examiner's statement, Hammond's predetermined position is not equivalent to Applicants' analyzing position. Hammond does not disclose or suggest that the sample holding parts can be opened and closed at the analyzing position as recited in Applicants' claims 18-23.

Accordingly, the invention of claims 18-23 is not suggested by the cited prior art, and the rejection of claims 18-23 under §103(a) is improper and should be withdrawn.

#### **IV. Claims 27 and 28**

Claim 27 is directed to an apparatus for use in analyzing pharmaceutical samples. Method claim 28 recites the apparatus of claim 1. The Office Action does not provide the statutory basis and supporting prior art for the rejection of claims 27 and 28.

Applicants submit that claims 27 and 28 are patentable over the prior art of record for the reasons given in the preceding Sections II(A) and III, respectively.

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**V. Summary**

Upon entry of this Amendment, claims 1-3, 6-23, and 25-28 are pending. Applicants respectfully submit that claims 1-3, 6-23, and 25-28 have been distinguished over the cited prior art, and are directed to patentable subject matter. Accordingly, Applicants request allowance of the claims.

**VI. Request for Examiner Interview**

To further prosecution and advance the application to allowance, Applicants respectfully request the Examiner to contact the undersigned Agent for a telephonic interview before issuance of the next Office Action.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: March 31, 2005

Respectfully submitted,



Andrew Fessak- Reg. No. 48,528  
Customer No. 07470- White & Case LLP  
Direct Line: (212) 819-8437